Free, Donna

From: Free, Donna
Sent: Tuesday, November 30, 2004 5:33 PM
To: 'Allen, Samie Niver'
Cc: Michael, Maher
Subject: RE: P030053a5 - physician training

HI Samie,

Attached please find Mentor's responses to your questions dated 11/29/04 regarding physician training and the registry Let us know if you require additional information.

Thanks

Donna

-----Original Message-----
From: Allen, Samie Niver [mailto:SXN@CDRH.FDA.GOV]
Sent: Tuesday, November 30, 2004 8:21 AM
To: 'Free, Donna'
Cc: 'Michael, Maher'
Subject: P030053a5 - physician training

This email supercedes yesterday's. With regard to your physician training/education initiatives, please provide the specific instructions/information you are going to give in terms of (1) your specific modes and causes of rupture findings and (2) rupture screening method and frequency for your product.

P030053a5

FDA questions dated 11/29/04 regarding patient registry and physician training

Registry:

With regard to your registry plans to contract with NaBIR, please clarify how these patient data are collected, the timepoints, and the actual list of all data/information collected for entry into the NaBIR.

That registry deficiency that I just sent should be expanded to cover both the TOPS and the embedded NaBIR.

You are proposing to not have a registry card. Please clarify if there is any other means by which are keeping track of the patients.

Voluntary Patient Registry Response:

The Tracking Outcomes in Plastic Surgery (referred to as "TOPS") registry, which collects plastic surgery procedural data, and clinical outcomes was developed by ASPS/PSEF. A breast implant registry is embedded within the Internet data-collection tool of TOPS. This registry (National Breast Implant Registry or "NaBIR") can track information, such as the number of implants placed or removed, clinical indications, type of facility, anesthesia administered, and short-term complications. The registry was designed to allow physicians to track implanted devices of their highly mobile patients.

Plastic Surgeons who are participating in the TOPS registry will ask the patients to participate in the voluntary patient registry. If the patient agrees, the physician will enter patient and surgery specific information in the TOPS database at the time of initial surgery. The physician completes the TOPS form denoting the type of initial surgery performed for the specific patient. The TOPS form is also completed at patient follow-up visits, where outcome data is recorded including complications. After completion of the TOPS form, the NaBIR form, specific to breast implant procedures is completed. The NaBIR form captures the following initial surgery information as well as explantation information:

- Patient identification information including address
- Implant manufacturer
- Implant type
- Implant shape
- Filler type
- Surgical Approach
- Incision Site
- Incision Size
- Explant Information including:
    - Years in vivo
    - Reason (Indication) for explant

Copies of the TOPS and NaBIR forms and an example of a summary report were included in Attachment 36 of the August 30, 2004 amendment. This implant registry will be implemented post-approval and will be funded by using a patient pass-through fee to NaBIR.

Mentor believes that TOPS and NaBIR data collection efforts will be the voluntary registry of choice to track patients and trace implant-related data and outcomes.

Patient device cards will be provided to the patient by the surgeon immediately following surgery.

Physician Training:

This email supercedes yesterday's. With regard to your physician training/ education initiatives, please provide the specific instructions/information you are going to give in terms of (1) your specific modes and causes of rupture findings and (2) rupture screening method and frequency for your product.

Physician Training Response:

As indicated in our August 30, 2004 response (amendment 5), Mentor is working cooperatively with the American Society of Plastic Surgeons (ASPS), the Plastic Surgery Education Foundation (PSEF) and the American Society of Aesthetic Plastic Surgeons (ASAPS) to develop a comprehensive physician training program. The physician education program (Silicone Breast Implant Education Symposium) will focus on surgical techniques, patient selection and monitoring, methods for the detection of ruptures, and the overall risks and complications associated with silicone gel-filled breast implants (Attachment 38). Mentor is collaborating and working on an on-going basis to update the presentation as relevant. This update will include a section pertaining to specific modes and causes of rupture findings. The photographs of the electron microscopy studies conducted by Dr. Brandon, and submitted in the August 30, 2004 amendment will be included in this segment on modes and causes of rupture. The photographs will depict the different types of defects resulting from sharp surgical instruments, localized shell fatigue (fold flaw damage), shell/patch junction failures and long failure lines of the product. This segment of the training program is in the process of being developed. Updates to this, and any other segment, can be made when new data are available.

The rupture screening method and frequency is described in a couple of sections of the draft training material provided. Please refer to the tab entitled "Patient Monitoring & Training, Accurate Initial Assessment." On pages 12 and 23 the presenter recommends self exams as well as annual doctor visits as well an imaging monitoring as indicated by age, family history and results of the

examination. Additionally, in the tab entitled "Leaking vs. Ruptured Silicone, Capsulectomy vs. Capsulotomy" local complications are discussed in detail. Please refer to pages 11-13 for complication information specifically related to ruptures and the diagnosis of ruptures.